

What is claimed is:

1. An orally dissolving film composition comprising:
  - a.) an enteric polymer;
  - b.) at least one alkaline buffering agent; and
  - c.) at least one active agent.
2. The film composition of claim 1 wherein the active agent is a nicotine active.
- 10 3. The film composition of claim 1 wherein said enteric polymer is pre-neutralized.
4. The film composition of claim 3 wherein said pre-neutralized enteric polymer is selected from the group consisting of cellulose acetate phthalate, hydroxypropyl methylcellulose phthalate, polyvinylacetate phthalate, poly(ethylacrylate 15 methacrylic acid) copolymer, shellac, hydroxypropyl methylcellulose acetate succinate, poly (methyl vinyl ether/maleic acid) monoethyl ester, and poly(methyl vinyl ether/maleic acid) n-butyl ester and mixtures thereof.
- 20 5. The film composition of claim 4 wherein the pre-neutralized enteric polymer is poly(ethylacrylate -methacrylic acid) copolymer.
6. The film composition of claim 1 wheren said alkaline buffering agent is selected from the group consisting of sodium carbonate, sodium bicarbonate, potassium carbonate, potassium bicarbonate, sodium phosphate dibasic, sodium phosphate 25 tribasic, potassium phosphate dibasic, potassium phosphate tribasic, calcium carbonate, magnesium carbonate, sodium hydroxide, magnesium hydroxide, potassium hydroxide, aluminium hydroxide, and mixtures thereof.
7. The film composition of claim 2 wherein said nicotine active is selected from the 30 group consisting of nicotine monotartrate, nicotine bitartrate, nicotine hydrochloride, nicotine dihydrochloride, nicotine sulfate, nicotine zinc chloride monohydrate, nicotine salicylate, nicotine oil, nicotine complexed with cyclodextrin, polymer resins such as nicotine polacrilex, and mixtures thereof.
- 35 8. The film composition of claim 7 wherein said nicotine active is nicotine oil.

9. The film of claim 2 wherein said alkaline buffering agent and said nicotine active are separately maintained within the film prior to oral administration.

5 10. The film composition of claim 1 further comprising a plasticizer.

11. A multi-component orally dissolving film comprising:

(a) a first component, comprising an alkaline buffering agent and a water-soluble filler; and

10 (b) a second component, comprising a nicotine active, an enteric polymer, and a plasticizer.

12. The film of claim 11, wherein the enteric polymer is pre-neutralized.

15 13. The film of claim 12 wherein said pre-neutralized enteric polymer is selected from the group consisting of cellulose acetate phthalate, hydroxypropyl methylcellulose phthalate, polyvinylacetate phthalate, poly(ethylacrylate methacrylic acid) copolymer, shellac, hydroxypropyl methylcellulose acetate succinate, poly (methyl vinyl ether/maleic acid) monoethyl ester, and poly(methyl 20 vinyl ether/maleic acid) n-butyl ester and mixtures thereof.

14. The film of claim 13 wherein the pre-neutralized enteric polymer is poly(ethylacrylate -methacrylic acid) copolymer.

25 15. The film of claim 11, wherein the second component further comprises an alkaline neutralizing agent.

16. The film of claim 15 wherein said alkaline buffering agent and said alkaline neutralizing agents are each selected from the group consisting of sodium 30 carbonate, sodium bicarbonate, potassium carbonate, potassium bicarbonate, sodium phosphate dibasic, sodium phosphate tribasic, potassium phosphate dibasic, potassium phosphate tribasic, calcium carbonate, magnesium carbonate, sodium hydroxide, magnesium hydroxide, potassium hydroxide, aluminium hydroxide, and mixtures thereof.

17. The film of claim 11 wherein said nicotine active is selected from the group consisting of nicotine monutartrate, nicotine bitartrate, nicotine hydrochloride, nicotine dihydrochloride, nicotine sulfate, nicotine zinc chloride monohydrate, nicotine salicylate, nicotine oil, nicotine complexed with cyclodextrin, polymer resins  
5 such as nicotine polacrilex, and mixtures thereof.
18. An orally dissolving film composition comprising: a first component comprising at least one enteric polymer, at least one alkaline buffering agent and at least one nicotine active in an amount effective to rapidly provide nicotine craving relief; and a  
10 second component comprising at least one bioadhesive polymer capable of forming a hydrogen bond with nicotine and at least one nicotine active in an amount effective to provide sustained nicotine craving relief.
19. The film composition of claim 18 wherein said enteric polymer is pre-  
15 neutralized.
20. The film composition of claim 19 wherein the pre-neutralized enteric polymer is selected from the group consisting of cellulose acetate phthalate, hydroxypropyl methylcellulose phthalate, polyvinylacetate phthalate, poly(ethylacrylate  
20 methacrylic acid) copolymer, shellac, hydroxypropyl methylcellulose acetate succinate, poly (methyl vinyl ether/maleic acid) monoethyl ester, and poly(methyl vinyl ether/maleic acid) n-butyl ester and mixtures thereof.
21. A method of providing rapid and sustained relief from nicotine cravings by  
25 administering to an individual in need thereof an orally dissolving film composition of claim 18.
22. A method of providing rapid relief from nicotine cravings by administering to an individual in need thereof an orally dissolving film composition of claim 11.  
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23. A method of reducing or eliminating tobacco consumption by an individual in need thereof by administering to the individual an orally dissolving film comprising at least one enteric polymer, at least one nicotine active and at least one alkaline buffering agent.

24. A method of providing rapid nicotine craving relief to an individual in need thereof by administering to the individual an orally dissolving film comprising at least one enteric polymer, at least one nicotine active and at least one alkaline buffering agent.

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25. An oral dosage form comprising:

- a.) at least one nicotine active;
- b.) at least one bioadhesive material capable of forming a hydrogen bond with the nicotine active; and
- c.) at least one rapidly releasing sensory impact agent;

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wherein the rapidly releasing sensory impact agent is present in an effective amount to provide rapid nicotine craving relief and wherein the dosage form provides both rapid and sustained craving relief to an individual in need thereof.

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26. The dosage form of claim 25 wherein the sensory impact agent is selected from the group consisting of: impact flavors, such as capsiacin, mustard, horseradish, ginger, wasabi, smoke, and black pepper; mild irritants, such as denicotinized smoke, citric acid, ascorbic acid; and mixtures thereof.

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27. The dosage form of claim 25 further comprising an alkaline buffering agent.

28. The dosage form of claim 25 further comprising a plasticizer.

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29. A method of providing rapid and sustained nicotine craving relief by administering to an individual in need thereof an oral dosage form comprising at least one nicotine active, at least one bioadhesive component and at least one rapidly releasing sensory impact agent, wherein the sensory impact agent is present in an effective amount to provide rapid craving relief to said individual.

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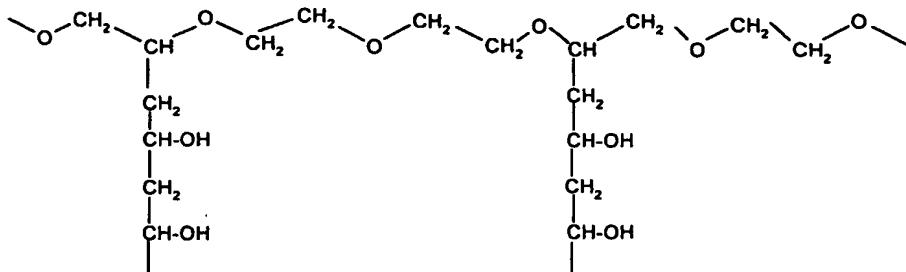
30. The method of claim 29 wherein the sensory impact agent is selected from the group consisting of: impact flavors, such as capsiacin, mustard, horseradish, ginger, wasabi, smoke, and black pepper; mild irritants, such as denicotinized smoke, citric acid, ascorbic acid; and mixtures thereof.

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31. An orally dissolving film comprising:

- a.) a cosmetic or pharmaceutical active; and
  - b.) a polyvinyl alcohol-polyethylene glycol graft copolymer of the general formula:

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32. The orally dissolving film composition of claim 31 wherein the cosmetic or therapeutic active is a nicotine active.

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33. A method of making an orally dissolving film composition comprising the steps of:

- (a) neutralizing an enteric polymer by mixing with an alkaline neutralizing agent in the presence of a solvent to render a polymeric mixture;
  - (b) further adding an active agent to the polymeric mixture;
  - (c) casting the polymeric mixture onto a suitable surface; and
  - (d) drying said polymeric mixture to render a polymeric film.

34. The process of claim 33, further comprising the following steps:

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- (e) dissolving an alkaline buffering agent and a water-soluble filler into water to render a buffer mixture
  - (f) casting the buffer mixture onto the polymeric film rendering a coated polymeric film
  - (g) drying said coated polymeric film.